IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVARTIS PHARMACEUTICALS CORPORATION

Plaintiff,

v.

Civil Action No. _____

ACCORD HEALTHCARE INC., INTAS PHARMACEUTICALS LIMITED, ALKEM LABORATORIES, LTD., S&B PHARMA, INC., AUROBINDO PHARMA LIMITED, AUROBINDO PHARMA USA, INC., BIOCON LIMITED, BIOCON PHARMA, INC.. BIONPHARMA INC., BRECKENRIDGE PHARMACEUTICAL, INC., STANDARD CHEMICAL & PHARMACEUTICAL CO., LTD., DR. REDDY'S LABORATORIES, INC., DR. REDDY'S LABORATORIES, LTD., EMCURE PHARMACEUTICALS, HERITAGE PHARMACEUTICALS INC., EZRA VENTURES, LLC, FIRST TIME US GENERICS LLC, GLENMARK PHARMACEUTICALS INC., USA, GLENMARK PHARMACEUTICALS LIMITED, HEC PHARM CO., LTD., HEC PHARM GROUP, HEC PHARM USA INC., HETERO USA INC, HETERO LABS LIMITED UNIT-V, HETERO LABS LIMITED, MYLAN PHARMACEUTICALS, INC., NOSTRUM LABORATORIES INC., NOSTRUM PHARMACEUTICALS, LLC, MSN LABORATORIES PRIVATE LIMITED, MSN PHARMACEUTICALS INC., PAR PHARMACEUTICAL INC., PRINSTON PHARMACEUTICAL INC., STRIDES GLOBAL PHARMA PRIVATE LIMITED, STRIDES PHARMA, INC., TORRENT PHARMA INC., TORRENT PHARMACEUTICALS LTD., ZYDUS PHARMACEUTICALS (USA) INC., and CADILA HEALTHCARE LIMITED

Defendants.

COMPLAINT

Novartis Pharmaceuticals Corporation ("Novartis") by its attorneys hereby alleges as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code. This action relates to Abbreviated New Drug Applications ("ANDAs") filed by the above-named defendants with the U.S. Food and Drug Administration ("FDA") for approval to engage in the commercial manufacture, use, or sale of Fingolimod 0.5 mg capsules, generic versions of Novartis's GILENYA® Capsules, 0.5 mg, prior to expiration of U.S. Patent No. 9,187,405 ("the '405 patent").

PARTIES

A. Novartis

2. Novartis Pharmaceuticals Corporation is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business in East Hanover, New Jersey.

B. The Generic Defendants

a) Accord Healthcare Inc.; Intas Pharmaceuticals Limited

3. Upon information and belief, Defendant Intas Pharmaceuticals Limited is a corporation organized and existing under the laws of India, having a principal place of business at Chinubhai Centre, Off. Nehru Bridge, Ashram Road, Ahmedabad 380009, Gujarat, India.

4. Upon information and belief, Defendant Accord Healthcare, Inc. is a corporation organized and existing under the laws of North Carolina, having a principal place of business at 1009 Slater Road, Suite 210-B, Durham, North Carolina 27703.

5. Upon information and belief, Intas Pharmaceuticals Limited is in the business of, among other things, developing, manufacturing, and selling generic versions of branded pharmaceutical products for the U.S. market. Upon information and belief, Accord Healthcare, Inc. is a wholly-owned subsidiary of Intas Pharmaceuticals Limited and is controlled and/or dominated by Intas Pharmaceuticals Limited. Upon information and belief, Accord Healthcare, Inc. develops, manufactures, and/or distributes generic drug products for marketing, sale, and/or use throughout the United States, including in this judicial district, at the direction, under the control, and for the benefit of Intas Pharmaceuticals Limited.

6. Intas Pharmaceuticals Limited and Accord Healthcare, Inc. are collectively referred to hereafter as "Accord" unless otherwise noted.

7. By a letter dated January 11, 2016, Accord notified Plaintiff that Accord had submitted to the FDA ANDA No. 207991 for Fingolimod 0.5 mg capsules, a drug product that is a generic version of GILENYA® ("Accord's ANDA Product"). The purpose of Accord's submission of the ANDA was to obtain approval under the Federal Food, Drug, and Cosmetic Act ("FDCA") to engage in the commercial manufacture, use, offer for sale, and/or sale of Accord's ANDA Product prior to the expiration of the '405 patent.

8. In its Notice Letter, Accord notified Plaintiff that, as a part of its ANDA, Accord had filed a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to the '405 patent asserting that the '405 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, and sale of Accord's ANDA Product.

9. Upon information and belief, and consistent with their past practices, Intas Pharmaceuticals Limited and Accord Healthcare, Inc. acted collaboratively in the preparation and submission of ANDA No. 207991.

10. Upon information and belief, and consistent with their past practices, following any FDA approval of ANDA No. 207991, Intas Pharmaceuticals Limited and Accord Healthcare, Inc. will work in concert with one another to make, use, offer to sell, and/or sell the generic drug products that are the subject of ANDA No. 207991 throughout the United States, and/or import such generic drug products into the United States, including in this judicial district.

11. Accord has committed an act of infringement in this judicial district by filing ANDA No. 207991 with the intent to make, use, offer to sell, and/or sell the generic drug products that are the subject of ANDA No. 207991 in this judicial district, an act of infringement that has led to foreseeable harm and injury to Novartis, a Delaware corporation.

12. Accord has extensive contacts with the State of Delaware, regularly conducts business in the State of Delaware, either directly or through one or more of its wholly owned subsidiaries, agents, and/or alter egos, has purposefully availed itself of the privilege of doing business in the State of Delaware, and intends to sell in the State of Delaware the product described in ANDA No. 207991 upon approval. Furthermore, upon information and belief, Accord has a regular and established place of business in this judicial district.

13. Intas Pharmaceuticals Limited and Accord Healthcare, Inc. have availed themselves of the legal protections of the State of Delaware by, among other things, admitting jurisdiction and asserting counterclaims in lawsuits filed in the United States District Court for the District of Delaware. *See e.g., Biogen International GmbH et al. v. Accord Healthcare Inc.*, C.A. No. 17-872 (D. Del.); *Bristol-Meyers Squibb Company et al. v. Accord Healthcare Inc.*,

C.A. No. 17-00398 (D. Del.); *Pfizer Inc. et al. v. Accord Healthcare, Inc. et al.*, C.A. No. 16-79 (D. Del.); *Forest Laboratories LLC, et al. v. Accord Healthcare Inc.*, C.A. No. 15-272 (D. Del.); *Cephalon Inc. v. Sandoz Inc. et al.*, C.A. No. 15-178 (D. Del.); *Cephalon, Inc. v. Accord Healthcare, Inc. et al.*, C.A. No. 13-2095 (D. Del.).

b) Alkem Laboratories, Ltd.; S&B Pharma, Inc.

14. Upon information and belief, Defendant Alkem Laboratories, Ltd. is a corporation organized and existing under the laws of India, having a principal place of business at Devashish Building, Alkem House, Senapti Bapat Road, Lower Parel, Mumbai, India 400 013.

15. Upon information and belief, Defendant S&B Pharma, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a registered agent for the service of process at The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801.

16. Upon information and belief, Alkem Laboratories, Ltd. is in the business of, among other things, developing, manufacturing, and selling generic versions of branded pharmaceutical products for the U.S. market. Upon information and belief, S&B Pharma, Inc. is a wholly-owned subsidiary of Alkem Laboratories, Ltd. and is controlled and/or dominated by Alkem Laboratories, Ltd. Upon information and belief, S&B Pharma, Inc. develops, manufactures and/or distributes generic drug products for marketing, sale, and/or use throughout the United States, including in this judicial district, at the direction, under the control, and for the benefit of Alkem Laboratories, Ltd.

17. Alkem Laboratories, Ltd. and S&B Pharma, Inc. are collectively referred to hereafter as "Alkem" unless otherwise noted.

18. By a letter dated December 27, 2016, Alkem notified Plaintiff that Alkem had submitted to the FDA ANDA No. 208004 for Fingolimod 0.5 mg capsules, a drug product that is a generic version of GILENYA® ("Alkem's ANDA Product"). The purpose of Alkem's submission of the ANDA was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Alkem's ANDA Product prior to the expiration of the '405 patent.

19. In its Notice Letter, Alkem notified Plaintiff that, as a part of its ANDA, Alkem had filed a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to the '405 patent asserting that the '405 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, and sale of Alkem's ANDA Product.

20. Upon information and belief, and consistent with their past practices, Intas Pharmaceuticals Limited and Accord Healthcare, Inc. acted collaboratively in the preparation and submission of ANDA No. 208004.

21. Upon information and belief, and consistent with their past practices, following any FDA approval of ANDA No. 208004, Alkem Laboratories, Ltd. and S&B Pharma, Inc. will work in concert with one another to make, use, offer to sell, and/or sell the generic drug products that are the subject of ANDA No. 208004 throughout the United States, and/or import such generic drug products into the United States, including in this judicial district.

22. Alkem has committed an act of infringement in this judicial district by filing ANDA No. 208004 with the intent to make, use, offer to sell, and/or sell the generic drug products that are the subject of ANDA No. 208004 in this judicial district, an act of infringement that has led to foreseeable harm and injury to Novartis, a Delaware corporation.

23. Alkem has extensive contacts with the State of Delaware, regularly conducts business in the State of Delaware, either directly or through one or more of its wholly owned subsidiaries, agents, and/or alter egos, has purposefully availed itself of the privilege of doing business in the State of Delaware, and intends to sell in the State of Delaware the product described in ANDA No. 208004 upon approval. Furthermore, upon information and belief, Alkem has a regular and established place of business in this judicial district.

24. Alkem Laboratories, Ltd. and S&B Pharma, Inc. have availed themselves of the legal protections of the State of Delaware by, among other things, admitting jurisdiction and asserting counterclaims in lawsuits filed in the United States District Court for the District of Delaware. *See, e.g.*, *H. Lundbeck A/S et al. v. Alkem Labs. Ltd.*, C.A. No. 18-00089 (D. Del.); *Takeda Pharmaceuticals U.S.A., Inc. v. Alkem Labs. Ltd.*, C.A. No. 18-00189 (D. Del.); *Bial-Portela & CA S.A. et al. v. Alkem Labs. Ltd. et al.*, C.A. No. 18-00304 (D. Del.); *Medicis Pharmaceutical Corp. v. Alkem Labs. Ltd.*, C.A. No. 12-01663 (D. Del.); *Pfizer Inc. et al. v. Alkem Labs. Ltd. et al.*, C.A. No. 13-01110 (D. Del.); *Sanofi et al. v. Alkem Labs. Ltd. et al.*, C.A. No. 14-00264 (D. Del.); *Sanofi et al. v. Alkem Labs. Ltd.*, C.A. No. 14-00292 (D. Del.); *Accorda Therapeutics Inc. et al. v. Alkem Labs. Ltd. et al.*, C.A. No. 14-00882 (D. Del.); *Accorda Therapeutics Inc. et al. v. Alkem Labs. Ltd.*, C.A. No. 14-00917 (D. Del.); *Sanofi et al. v. Alkem Labs. Ltd. et al.*, C.A. No. 15-00415 (D. Del.); *Sanofi et al. v. Alkem Labs. Ltd.*, C.A. No. 15-01200 (D. Del.); *Shire Development LLC et al. v. Alkem Labs. Ltd.*, C.A. No. 16-00747 (D. Del.); *Amgen Inc. v. Alkem Labs. Ltd.*, C.A. No. 17-00815 (D. Del.); *Biogen Int'l GmbH et al. v. Alkem Labs. Ltd. et al.*, C.A. No. 17-00850 (D. Del.); *Insys Therapeutics, Inc. et al. v. Alkem Labs. Ltd. et al.*, C.A. No. 17-01419 (D. Del.); *Biogen Int'l GmbH et al. v. Alkem Labs. Ltd. et al.*, C.A. No. 17-00823 (D. Del.).

c) Aurobindo Pharma Limited; Aurobindo Pharma USA, Inc.

25. Upon information and belief, Defendant Aurobindo Pharma Limited is a corporation organized and existing under the laws of India, having a principal place of business at Plot No. 2, Maitri Vihar, Ameerpet, Hyderabad – 500038, Andhra Pradesh, India and a corporate office at Water Mark Building, Plot No. 11, Survey No. 9, Kondapur, Hitech City, Hyderabad - 500084, Telangana, India.

26. Upon information and belief, Defendant Aurobindo Pharma USA, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 279 Princeton-Hightstown Road, East Windsor, New Jersey 08520.

27. Upon information and belief, Aurobindo Pharma Limited is in the business of, among other things, developing, manufacturing, and selling generic versions of branded pharmaceutical products for the U.S. market. Upon information and belief, Aurobindo Pharma USA, Inc. is a wholly-owned subsidiary of Aurobindo Pharma Limited and is controlled and/or dominated by Aurobindo Pharma Limited. Upon information and belief, Aurobindo Pharma USA, Inc. develops, manufactures and/or distributes generic drug products for marketing, sale, and/or use throughout the United States, including in this judicial district, at the direction, under the control, and for the benefit of Aurobindo Pharma Limited.

28. Aurobindo Pharma Limited and Aurobindo Pharma USA, Inc. are collectively referred to hereafter as "Aurobindo" unless otherwise noted.

29. By a letter dated February 18, 2016, Aurobindo notified Plaintiff that Aurobindo had submitted to the FDA ANDA No. 207983 for Fingolimod 0.5 mg capsules, a drug product that is a generic version of GILENYA® ("Aurobindo's ANDA Product"). The purpose of Aurobindo's submission of the ANDA was to obtain approval under the FDCA to

engage in the commercial manufacture, use, offer for sale, and/or sale of Aurobindo's ANDA Product prior to the expiration of the '405 patent.

30. In its Notice Letter, Aurobindo notified Plaintiff that, as a part of its ANDA, Aurobindo had filed a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to the '405 patent asserting that the '405 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, and sale of Aurobindo's ANDA Product.

31. Upon information and belief, and consistent with their past practices, Aurobindo Pharma Limited and Aurobindo Pharma USA, Inc. acted collaboratively in the preparation and submission of ANDA No. 207983.

32. Upon information and belief, and consistent with their past practices, following any FDA approval of ANDA No. 207983, Aurobindo Pharma Limited and Aurobindo Pharma USA, Inc., Inc. will work in concert with one another to make, use, offer to sell, and/or sell the generic drug products that are the subject of ANDA No. 207983 throughout the United States, and/or import such generic drug products into the United States, including in this judicial district.

33. Aurobindo has committed an act of infringement in this judicial district by filing ANDA No. 207983 with the intent to make, use, offer to sell, and/or sell the generic drug products that are the subject of ANDA No. 207983 in this judicial district, an act of infringement that has led to foreseeable harm and injury to Novartis, a Delaware corporation.

34. Aurobindo has extensive contacts with the State of Delaware, regularly conducts business in the State of Delaware, either directly or through one or more of its wholly owned subsidiaries, agents, and/or alter egos, has purposefully availed itself of the privilege of

doing business in the State of Delaware, and intends to sell in the State of Delaware the product described in ANDA No. 207983 upon approval. Furthermore, upon information and belief, Aurobindo has a regular and established place of business in this judicial district.

35. Aurobindo Pharma Limited and Aurobindo Pharma USA, Inc. have availed themselves of the legal protections of the State of Delaware by, among other things, admitting jurisdiction and asserting counterclaims in lawsuits filed in the United States District Court for the District of Delaware. *See, e.g.*, *Allergan Sales, LLC et al. v. Aurobindo Pharma USA, Inc. et al*., C.A. No. 18-00118 (D. Del.); *Forest Laboratories, LLC et al. v. Aurobindo Pharma Ltd. et al.*, C.A. No. 17-01210 (D. Del.); *Kissei Pharm. Co., Ltd. et al. v. Aurobindo Pharma Ltd. et al.*, C.A. No. 17-01161 (D. Del.).

d) Biocon Limited; Biocon Pharma, Inc.

36. Upon information and belief, Defendant Biocon Limited is a corporation organized and existing under the laws of India, having a principal place of business at 20th KM, Hosur Road, Electronic City, Bangalore, 560034, India.

37. Upon information and belief, Defendant Biocon Pharma, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 485 US Highway 1 S B305, Iselin, New Jersey 08830.

38. Upon information and belief, Biocon Limited is in the business of, among other things, developing, manufacturing, and selling generic versions of branded pharmaceutical products for the U.S. market. Upon information and belief, Biocon Pharma, Inc. is a wholly-owned subsidiary of Biocon Limited and is controlled and/or dominated by Biocon Limited. Upon information and belief, Biocon Pharma, Inc. develops, manufactures and/or distributes

generic drug products for marketing, sale, and/or use throughout the United States, including in this judicial district, at the direction, under the control, and for the benefit of Biocon Limited.

39. Biocon Limited and Biocon Pharma, Inc. are collectively referred to hereafter as "Biocon" unless otherwise noted.

40. By a letter dated April 18, 2016, Biocon notified Plaintiff that Biocon had submitted to the FDA ANDA No. 207979 for Fingolimod 0.5 mg capsules, a drug product that is a generic version of GILENYA® ("Biocon's ANDA Product"). The purpose of Biocon's submission of the ANDA was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Biocon's ANDA Product prior to the expiration of the '405 patent.

41. In its Notice Letter, Biocon notified Plaintiff that, as a part of its ANDA, Biocon had filed a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to the '405 patent asserting that the '405 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, and sale of Biocon's ANDA Product.

42. Upon information and belief, and consistent with their past practices, Biocon Limited and Biocon Pharma, Inc. acted collaboratively in the preparation and submission of ANDA No. 207979.

43. Upon information and belief, and consistent with their past practices, following any FDA approval of ANDA No. 207979, Biocon Limited and Biocon Pharma, Inc., Inc. will work in concert with one another to make, use, offer to sell, and/or sell the generic drug products that are the subject of ANDA No. 207979 throughout the United States, and/or import such generic drug products into the United States, including in this judicial district.

44. Biocon has committed an act of infringement in this judicial district by filing ANDA No. 207979 with the intent to make, use, offer to sell, and/or sell the generic drug products that are the subject of ANDA No. 207979 in this judicial district, an act of infringement that has led to foreseeable harm and injury to Novartis, a Delaware corporation.

45. Biocon has extensive contacts with the State of Delaware, regularly conducts business in the State of Delaware, either directly or through one or more of its wholly owned subsidiaries, agents, and/or alter egos, has purposefully availed itself of the privilege of doing business in the State of Delaware, and intends to sell in the State of Delaware the product described in ANDA No. 207979 upon approval. Furthermore, upon information and belief, Biocon has a regular and established place of business in this judicial district.

46. Biocon Limited and Biocon Pharma, Inc. have availed themselves of the legal protections of the State of Delaware by, among other things, admitting jurisdiction and asserting counterclaims in lawsuits filed in the United States District Court for the District of Delaware. *See, e.g.*, *Teva Pharmaceuticals USA Inc. et al. v. Biocon Ltd. et al.*, C.A. No. 16-00278 (D. Del.); *Sanofi-Aventis U.S. LLC et al. v. Biocon Ltd.*, C.A. No. 17-00003 (D. Del.).

e) Bionpharma Inc.

47. Upon information and belief, Defendant Bionpharma Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 600 Alexander Road, Suite 2-4B, Princeton, NJ 08540.

48. Upon information and belief, Bionpharma Inc. is in the business of, among other things, developing, manufacturing, and selling generic versions of branded pharmaceutical products for the U.S. market, including in this district.

49. Bionpharma Inc. is referred to hereafter as "Bionpharma" unless otherwise noted.

50. By a letter dated June 8, 2017, Bionpharma notified Plaintiff that Bionpharma had submitted to the FDA ANDA No. 210252 for Fingolimod 0.5 mg capsules, a drug product that is a generic version of GILENYA® ("Bionpharma's ANDA Product"). The purpose of Bionpharma's submission of the ANDA was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Bionpharma's ANDA Product prior to the expiration of the '405 patent.

51. In its Notice Letter, Bionpharma notified Plaintiff that, as a part of its ANDA, Bionpharma had filed a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to the '405 patent asserting that the '405 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, and sale of Bionpharma's ANDA Product.

52. Upon information and belief, and consistent with its past practices, following any FDA approval of ANDA No. 210252, Bionpharma will make, use, offer to sell, and/or sell the generic drug products that are the subject of ANDA No. 210252 throughout the United States, and/or import such generic drug products into the United States, including in this judicial district.

53. Bionpharma has committed an act of infringement in this judicial district by filing ANDA No. 210252 with the intent to make, use, offer to sell, and/or sell the generic drug products that are the subject of ANDA No. 210252 in this judicial district, an act of infringement that has led to foreseeable harm and injury to Novartis, a Delaware corporation.

54. Bionpharma has extensive contacts with the State of Delaware, regularly conducts business in the State of Delaware, either directly or through one or more of its wholly owned subsidiaries, agents, and/or alter egos, has purposefully availed itself of the privilege of doing business in the State of Delaware, and intends to sell in the State of Delaware the product described in ANDA No. 210252 upon approval. Furthermore, upon information and belief, Bionpharma has a regular and established place of business in this judicial district.

55. Bionpharma has availed itself of the legal protections of the State of Delaware by, among other things, admitting jurisdiction and asserting counterclaims in lawsuits filed in the United States District Court for the District of Delaware. *See, e.g., Patheon Softgels Inc. et al. v. Apotex Inc. et al.*, 18-00003 (D. Del.); *Bristol-Myers Squibb Company et al. v. Bionpharma Inc.*, 17-00400 (D. Del.); *Silvergate Pharmaceuticals Inc. v. Bionpharma Inc.*, 16-00876 (D. Del.).

f) Breckenridge Pharmaceutical, Inc.; Standard Chemical & Pharmaceutical Co., Ltd.

56. Upon information and belief, Defendant Standard Chemical & Pharmaceutical Co., Ltd. is a corporation organized and existing under the laws of Taiwan, having a principal place of business at No. 154 Kaiyuan Road, Sinying District, Tainan City, Taiwan.

57. Upon information and belief, Defendant Breckenridge Pharmaceutical, Inc. is a corporation organized and existing under the laws of the State of Florida, having a principal place of business at 6111 Broken Sound Parkway, NW Suite 170, Boca Raton, FL.

58. Upon information and belief, Standard Chemical & Pharmaceutical Co., Ltd. and Breckenridge Pharmaceutical, Inc. are in the business of, among other things,

developing, manufacturing, and selling generic versions of branded pharmaceutical products for the U.S. market, including in this district.

59. Standard Chemical & Pharmaceutical Co., Ltd. and Breckenridge Pharmaceutical, Inc. are collectively referred to hereafter as "Breckenridge" unless otherwise noted.

60. By a letter dated May 25, 2016, Breckenridge notified Plaintiff that Breckenridge had submitted to the FDA ANDA No. 207940 for Fingolimod 0.5 mg capsules, a drug product that is a generic version of GILENYA® ("Breckenridge's ANDA Product"). The purpose of Breckenridge's submission of the ANDA was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Breckenridge's ANDA Product prior to the expiration of the '405 patent.

61. In its Notice Letter, Breckenridge notified Plaintiff that, as a part of its ANDA, Breckenridge had filed a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to the '405 patent asserting that the '405 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, and sale of Breckenridge's ANDA Product.

62. Upon information and belief, Standard Chemical & Pharmaceutical Co., Ltd. and Breckenridge Pharmaceutical, Inc. acted collaboratively in the preparation and submission of ANDA No. 207940.

63. Upon information and belief, and consistent with their past practices, following any FDA approval of ANDA No. 207940, Standard Chemical & Pharmaceutical Co., Ltd. and Breckenridge Pharmaceutical, Inc., Inc. will work in concert with one another to make, use, offer to sell, and/or sell the generic drug products that are the subject of ANDA No. 207940

throughout the United States, and/or import such generic drug products into the United States, including in this judicial district.

64. Breckenridge has committed an act of infringement in this judicial district by filing ANDA No. 207940 with the intent to make, use, offer to sell, and/or sell the generic drug products that are the subject of ANDA No. 207940 in this judicial district, an act of infringement that has led to foreseeable harm and injury to Novartis, a Delaware corporation.

65. Breckenridge has extensive contacts with the State of Delaware, regularly conducts business in the State of Delaware, either directly or through one or more of its wholly owned subsidiaries, agents, and/or alter egos, has purposefully availed itself of the privilege of doing business in the State of Delaware, and intends to sell in the State of Delaware the product described in ANDA No. 207940 upon approval. Furthermore, upon information and belief, Breckenridge has a regular and established place of business in this judicial district.

66. Breckenridge has availed itself of the legal protections of the State of Delaware by, among other things, admitting jurisdiction and asserting counterclaims in lawsuits filed in the United States District Court for the District of Delaware. *See, e.g., Onyx Therapeutics, Inc. v. Breckenridge Pharma., Inc.*, C.A. No. 18-00262 (D. Del.); *Forest Labs., LLC f/k/a Forest Labs., Inc. et al. v. Breckenridge Pharm., Inc.*, C.A. No. 14-1504 (D. Del.); *Novartis Pharms. Corp. v. Breckenridge Pharm., Inc.*, C.A. No. 14-1043 (D. Del.); *Par Pharm. Inc. et al. v. Breckenridge Pharm. Inc.*, C.A. No. 13-1114 (D. Del.); *Onyx Therapeutics, Inc. v. Breckenridge Pharm. Inc.*, C.A. No. 16-1001 (D. Del.).

g) Dr. Reddy's Laboratories, Inc.; Dr. Reddy's Laboratories, Ltd.

67. Upon information and belief, Defendant Dr. Reddy's Laboratories, Ltd. is a corporation organized and existing under the laws of India, having a principal place of business at 8-2-337 Road No. 3, Banjara Hills, Hyderabad, 500034, India.

68. Upon information and belief, Defendant Dr. Reddy's Laboratories, Inc. is a corporation organized and existing under the laws of the State of New Jersey, having a principal place of business at 107 College Road East, Princeton, New Jersey 08540.

69. Upon information and belief, Dr. Reddy's Laboratories, Ltd. is in the business of, among other things, developing, manufacturing, and selling generic versions of branded pharmaceutical products for the U.S. market. Upon information and belief, Dr. Reddy's Laboratories, Inc. is a wholly-owned subsidiary of Dr. Reddy's Laboratories, Ltd. and is controlled and/or dominated by Dr. Reddy's Laboratories, Ltd. Upon information and belief, Dr. Reddy's Laboratories, Inc. develops, manufactures and/or distributes generic drug products for marketing, sale, and/or use throughout the United States, including in this judicial district, at the direction, under the control, and for the benefit of Dr. Reddy's Laboratories, Ltd.

70. Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. are collectively referred to hereafter as "Dr. Reddy's" unless otherwise noted.

71. By a letter dated April 12, 2016, Dr. Reddy's notified Plaintiff that Dr. Reddy's had submitted to the FDA ANDA No. 208000 for Fingolimod 0.5 mg capsules, a drug product that is a generic version of GILENYA® ("Dr. Reddy's ANDA Product"). The purpose of Dr. Reddy's submission of the ANDA was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Dr. Reddy's ANDA Product prior to the expiration of the '405 patent.

72. In its Notice Letter, Dr. Reddy's notified Plaintiff that, as a part of its ANDA, Dr. Reddy's had filed a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to the '405 patent asserting that the '405 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, and sale of Dr. Reddy's ANDA Product.

73. Upon information and belief, and consistent with their past practices, Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. acted collaboratively in the preparation and submission of ANDA No. 208000.

74. Upon information and belief, and consistent with their past practices, following any FDA approval of ANDA No. 208000, Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. will work in concert with one another to make, use, offer to sell, and/or sell the generic drug products that are the subject of ANDA No. 208000 throughout the United States, and/or import such generic drug products into the United States, including in this judicial district.

75. Dr. Reddy's has committed an act of infringement in this judicial district by filing ANDA No. 208000 with the intent to make, use, offer to sell, and/or sell the generic drug products that are the subject of ANDA No. 208000 in this judicial district, an act of infringement that has led to foreseeable harm and injury to Novartis, a Delaware corporation.

76. Dr. Reddy's has extensive contacts with the State of Delaware, regularly conducts business in the State of Delaware, either directly or through one or more of its wholly owned subsidiaries, agents, and/or alter egos, has purposefully availed itself of the privilege of doing business in the State of Delaware, and intends to sell in the State of Delaware the product

described in ANDA No. 208000 upon approval. Furthermore, upon information and belief, Dr. Reddy's has a regular and established place of business in this judicial district.

77. Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. have availed themselves of the legal protections of the State of Delaware by, among other things, admitting jurisdiction and asserting counterclaims in lawsuits filed in the United States District Court for the District of Delaware. *See, e.g.*, *Onyx Therapeutics, Inc. v. Dr. Reddy's Laboratories, Inc. et al.*, 17-01811 (D. Del.), *Bristol-Myers Squibb Company et al. v. Dr. Reddy's Laboratories, Ltd. et al.*, 17-00401 (D. Del.), *Teva Pharmaceuticals USA, Inc. et al v. Dr. Reddy's Laboratories, Ltd. et al.*, 16-01267 (D. Del.), *Onyx Therapeutics, Inc. v. Dr. Reddy's Laboratories, Inc. et al.*, 16-01011 (D. Del.), *Amgen Inc. v. Dr. Reddy's Laboratories, Ltd. et al.*, 16-00900 (D. Del.), *Pfizer Inc. et al v. Dr. Reddy's Laboratories, Ltd. et al.*, 15-01067 (D. Del.), *Novartis Pharmaceuticals Corporation et al v. Dr. Reddy's Laboratories, Ltd. et al.*, 15-01026, *Galderma Laboratories, LP et al. v. Dr. Reddy's Laboratories, Ltd. et al.* 15-00670 (D. Del.), and *Cephalon, Inc. v. Dr. Reddy's Laboratories, Ltd. et al.*, 15-00179 (D. Del.).

h) Emcure Pharmaceuticals; Heritage Pharmaceuticals Inc.

78. Upon information and belief, Defendant Emcure Pharmaceuticals is a corporation organized and existing under the laws of India, having a principal place of business at Emcure House, T184, M.I.D.C., Bhosari, Pune, 411026, Maharashtra, India.

79. Upon information and belief, Defendant Heritage Pharmaceuticals Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 12 Christopher Way, Suite 300, Eatontown, New Jersey 07724.

80. Upon information and belief, Emcure Pharmaceuticals is in the business of, among other things, developing, manufacturing, and selling generic versions of branded

pharmaceutical products for the U.S. market. Upon information and belief, Heritage Pharmaceuticals Inc. is a wholly-owned subsidiary of Emcure Pharmaceuticals and is controlled and/or dominated by Emcure Pharmaceuticals. Upon information and belief, Heritage Pharmaceuticals Inc. develops, manufactures and/or distributes generic drug products for marketing, sale, and/or use throughout the United States, including in this judicial district, at the direction, under the control, and for the benefit of Emcure Pharmaceuticals.

81. Emcure Pharmaceuticals and Heritage Pharmaceuticals Inc. are collectively referred to hereafter as "Emcure" unless otherwise noted.

82. By a letter dated March 1, 2016, Emcure notified Plaintiff that Emcure had submitted to the FDA ANDA No. 207927 for Fingolimod 0.5 mg capsules, a drug product that is a generic version of GILENYA® ("Emcure's ANDA Product"). The purpose of Emcure's submission of the ANDA was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Emcure's ANDA Product prior to the expiration of the '405 patent.

83. In its Notice Letter, Emcure notified Plaintiff that, as a part of its ANDA, Emcure had filed a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to the '405 patent asserting that the '405 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, and sale of Emcure's ANDA Product.

84. Upon information and belief, and consistent with their past practices, Emcure Pharmaceuticals and Heritage Pharmaceuticals Inc. acted collaboratively in the preparation and submission of ANDA No. 207927.

85. Upon information and belief, and consistent with their past practices, following any FDA approval of ANDA No. 207927, Emcure Pharmaceuticals and Heritage Pharmaceuticals Inc., Inc. will work in concert with one another to make, use, offer to sell, and/or sell the generic drug products that are the subject of ANDA No. 207927 throughout the United States, and/or import such generic drug products into the United States, including in this judicial district.

86. Emcure has committed an act of infringement in this judicial district by filing ANDA No. 207927 with the intent to make, use, offer to sell, and/or sell the generic drug products that are the subject of ANDA No. 207927 in this judicial district, an act of infringement that has led to foreseeable harm and injury to Novartis, a Delaware corporation.

87. Emcure has extensive contacts with the State of Delaware, regularly conducts business in the State of Delaware, either directly or through one or more of its wholly owned subsidiaries, agents, and/or alter egos, has purposefully availed itself of the privilege of doing business in the State of Delaware, and intends to sell in the State of Delaware the product described in ANDA No. 207927 upon approval. Furthermore, upon information and belief, Emcure has a regular and established place of business in this judicial district.

88. Emcure Pharmaceuticals and Heritage Pharmaceuticals Inc. have availed themselves of the legal protections of the State of Delaware by, among other things, admitting jurisdiction and asserting counterclaims in lawsuits filed in the United States District Court for the District of Delaware. *See, e.g.*, *Bristol-Myers Squibb Company et al. v. Emcure Pharmaceuticals Ltd.*, 17-00402 (D. Del.); *Cephalon, Inc. v. Emcure Pharmaceuticals, Ltd. et al.*, C.A. No. 14-0335 (D. Del.).

i) Ezra Ventures, LLC

89. Upon information and belief, Defendant Ezra Ventures, LLC is a corporation organized and existing under the laws of the State of Arkansas, having a principal place of business at 401 S. Cedar Street, Little Rock, Arkansas, 72205.

90. Upon information and belief, Ezra Ventures, LLC is in the business of, among other things, developing, manufacturing, and selling generic versions of branded pharmaceutical products for the U.S. market, including in this district.

91. Ezra Ventures, LLC is referred to hereafter as "Ezra" unless otherwise noted.

92. By a letter dated February 2, 2017, Ezra notified Plaintiff that Ezra had submitted to the FDA ANDA No. 207945 for Fingolimod 0.5 mg capsules, a drug product that is a generic version of GILENYA® ("Ezra's ANDA Product"). The purpose of Ezra's submission of the ANDA was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Ezra's ANDA Product prior to the expiration of the '405 patent.

93. In its Notice Letter, Ezra notified Plaintiff that, as a part of its ANDA, Ezra had filed a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to the '405 patent asserting that the '405 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, and sale of Ezra's ANDA Product.

94. Upon information and belief, and consistent with its past practices, following any FDA approval of ANDA No. 207945, Ezra will make, use, offer to sell, and/or sell the generic drug products that are the subject of ANDA No. 207945 throughout the United States, and/or import such generic drug products into the United States, including in this judicial district.

95. Ezra has committed an act of infringement in this judicial district by filing ANDA No. 207945 with the intent to make, use, offer to sell, and/or sell the generic drug products that are the subject of ANDA No. 207945 in this judicial district, an act of infringement that has led to foreseeable harm and injury to Novartis, a Delaware corporation.

96. Ezra has availed itself of the legal protections of the State of Delaware by, among other things, admitting jurisdiction and asserting counterclaims in lawsuits field in the United States District Court for the District of Delaware. *See, e.g., Novartis AG et al. v. Ezra Ventures, LLC*, C.A. No. 15-00150 (D. Del.). Ezra has extensive contacts with the State of Delaware, regularly conducts business in the State of Delaware, either directly or through one or more of its wholly owned subsidiaries, agents, and/or alter egos, has purposefully availed itself of the privilege of doing business in the State of Delaware, and intends to sell in the State of Delaware the product described in ANDA No. 207945 upon approval.

j) First Time US Generics LLC

97. Upon information and belief, Defendant First Time US Generics LLC is a limited liability company organized and existing under the laws of the State of Delaware, having a principal place of business at 505 Park Way, Suite 6, Broomall, Pennsylvania 19008.

98. Upon information and belief, First Time US Generics LLC is in the business of, among other things, developing, manufacturing, and selling generic versions of branded pharmaceutical products for the U.S. market, including in this district.

99. First Time US Generics LLC is referred to hereafter as "First Time" unless otherwise noted.

100. By a letter dated February 29, 2016, First Time notified Plaintiff that First Time had submitted to the FDA ANDA No. 207941 for Fingolimod 0.5 mg capsules, a drug

product that is a generic version of GILENYA® ("First Time's ANDA Product"). The purpose of First Time's submission of the ANDA was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of First Time's ANDA Product prior to the expiration of the '405 patent.

101. In its Notice Letter, First Time notified Plaintiff that, as a part of its ANDA, First Time had filed a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to the '405 patent asserting that the '405 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, and sale of First Time's ANDA Product.

102. Upon information and belief, and consistent with its past practices, following any FDA approval of ANDA No. 207941, First Time will make, use, offer to sell, and/or sell the generic drug products that are the subject of ANDA No. 207941 throughout the United States, and/or import such generic drug products into the United States, including in this judicial district.

103. First Time has committed an act of infringement in this judicial district by filing ANDA No. 207941 with the intent to make, use, offer to sell, and/or sell the generic drug products that are the subject of ANDA No. 207941 in this judicial district, an act of infringement that has led to foreseeable harm and injury to Novartis, a Delaware corporation.

104. First Time has extensive contacts with the State of Delaware, regularly conducts business in the State of Delaware, either directly or through one or more of its wholly owned subsidiaries, agents, and/or alter egos, has purposefully availed itself of the privilege of doing business in the State of Delaware, and intends to sell in the State of Delaware the product

described in ANDA No. 207941 upon approval. Furthermore, upon information and belief, First Time has a regular and established place of business in this judicial district.

105. First Time has availed itself of the legal protections of the State of Delaware by, among other things, admitting jurisdiction and asserting counterclaims in lawsuits filed in the United States District Court for the District of Delaware. *See, e.g.*, *Sanofi S.A. v. First Time US Generics LLC,* Civ. No. 14-293 (D. Del.); *Forest Labs. Inc. v. First Time US Generics LLC,* Civ. No. 13-1642 (D. Del.).

k) Glenmark Pharmaceuticals Inc., USA; Glenmark Pharmaceuticals Limited

106. Upon information and belief, Defendant Glenmark Pharmaceuticals Limited is a corporation organized and existing under the laws of India, having a principal place of business at Glenmark House, HDO-Corporate Building, Wing -A, B D Sawant Marg, Chakala, Off Western Express Highway, Mumbai 400099, Maharashtra, India.

107. Upon information and belief, Defendant Glenmark Pharmaceuticals Inc., USA is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 750 Corporate Drive, Mahwah, New Jersey 07430.

108. Upon information and belief, Glenmark Pharmaceuticals Limited is in the business of, among other things, developing, manufacturing, and selling generic versions of branded pharmaceutical products for the U.S. market. Upon information and belief, Glenmark Pharmaceuticals Inc., USA is a wholly-owned subsidiary of Glenmark Pharmaceuticals Limited and is controlled and/or dominated by Glenmark Pharmaceuticals Limited. Upon information and belief, Glenmark Pharmaceuticals Inc., USA develops, manufactures and/or distributes generic drug products for marketing, sale, and/or use throughout the United States, including in

this judicial district, at the direction, under the control, and for the benefit of Glenmark Pharmaceuticals Limited.

109. Glenmark Pharmaceuticals Limited and Glenmark Pharmaceuticals Inc., USA are collectively referred to hereafter as "Glenmark" unless otherwise noted.

110. By a letter dated October 6, 2016, Glenmark notified Plaintiff that Glenmark had submitted to the FDA ANDA No. 207985 for Fingolimod 0.5 mg capsules, a drug product that is a generic version of GILENYA® ("Glenmark's ANDA Product"). The purpose of Glenmark's submission of the ANDA was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Glenmark's ANDA Product prior to the expiration of the '405 patent.

111. In its Notice Letter, Glenmark notified Plaintiff that, as a part of its ANDA, Glenmark had filed a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to the '405 patent asserting that the '405 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, and sale of Glenmark's ANDA Product.

112. Upon information and belief, and consistent with their past practices, Glenmark Pharmaceuticals Limited and Glenmark Pharmaceuticals Inc., USA acted collaboratively in the preparation and submission of ANDA No. 207985.

113. Upon information and belief, and consistent with their past practices, following any FDA approval of ANDA No. 207985, Glenmark Pharmaceuticals Limited and Glenmark Pharmaceuticals Inc., USA, Inc. will work in concert with one another to make, use, offer to sell, and/or sell the generic drug products that are the subject of ANDA No. 207985

throughout the United States, and/or import such generic drug products into the United States, including in this judicial district.

114. Glenmark has committed an act of infringement in this judicial district by filing ANDA No. 207985 with the intent to make, use, offer to sell, and/or sell the generic drug products that are the subject of ANDA No. 207985 in this judicial district, an act of infringement that has led to foreseeable harm and injury to Novartis, a Delaware corporation.

115. Glenmark has extensive contacts with the State of Delaware, regularly conducts business in the State of Delaware, either directly or through one or more of its wholly owned subsidiaries, agents, and/or alter egos, has purposefully availed itself of the privilege of doing business in the State of Delaware, and intends to sell in the State of Delaware the product described in ANDA No. 207985 upon approval. Furthermore, upon information and belief, Glenmark has a regular and established place of business in this judicial district.

116. Glenmark Pharmaceuticals Limited and Glenmark Pharmaceuticals Inc., USA have availed themselves of the legal protections of the State of Delaware by, among other things, admitting jurisdiction and asserting counterclaims in lawsuits filed in the United States District Court for the District of Delaware. *See, e.g., Glenmark Pharmaceuticals Ltd et al. v. GlaxoSmithKline PLC et al.*, C.A. No. 13-00135 (D. Del.); *Delcor Asset Corporation v. Glenmark Pharmaceuticals et al.*, C.A. No. 18-00460 (D. Del.).

l) HEC Pharm Co., Ltd.; HEC Pharm Group; HEC Pharm USA Inc.

117. Upon information and belief, Defendant HEC Pharm Group is a corporation organized and existing under the laws of China, having a principal place of business at Dong Yang Guang Park, Shangsha, Chang'an, Dongguan, Guangdong, 523871, China.

118. Upon information and belief, Defendant HEC Pharm Co., Ltd. is a corporation organized and existing under the laws of China, having a principal place of business at Binjiang Road 62, Yidu, Yichang, 443300, Hubei, China.

119. Upon information and belief, Defendant HEC Pharm USA Inc. is a corporation organized and existing under the laws of the State of New Jersey, having a principal place of business at 116 Village Blvd, Suite 200, Princeton, NJ 08540.

120. Upon information and belief, HEC Pharm Group is in the business of, among other things, developing, manufacturing, and selling generic versions of branded pharmaceutical products for the U.S. market. Upon information and belief, HEC Pharm USA Inc. and HEC Pharm Co., Ltd. are wholly-owned subsidiaries of HEC Pharm Group and are controlled and/or dominated by HEC Pharm Group. Upon information and belief, HEC Pharm USA Inc. develops, manufactures and/or distributes generic drug products for marketing, sale, and/or use throughout the United States, including in this judicial district, at the direction, under the control, and for the benefit of HEC Pharm Group and HEC Pharm Co., Ltd.

121. HEC Pharm Group, HEC Pharm Co., Ltd., and HEC Pharm USA Inc. are collectively referred to hereafter as "HEC" unless otherwise noted.

122. By a letter dated January 28, 2016, HEC notified Plaintiff that HEC had submitted to the FDA ANDA No. 207939 for Fingolimod 0.5 mg capsules, a drug product that is a generic version of GILENYA® ("HEC's ANDA Product"). The purpose of HEC's submission of the ANDA was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of HEC's ANDA Product prior to the expiration of the '405 patent.

123. In its Notice Letter, HEC notified Plaintiff that, as a part of its ANDA, HEC had filed a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA,

21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to the '405 patent asserting that the '405 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, and sale of HEC's ANDA Product.

124. Upon information and belief, and consistent with their past practices, HEC Pharm Group, HEC Pharm Co., Ltd., and HEC Pharm USA Inc. acted collaboratively in the preparation and submission of ANDA No. 207939.

125. Upon information and belief, and consistent with their past practices, following any FDA approval of ANDA No. 207939, HEC Pharm Group, HEC Pharm Co., Ltd., and HEC Pharm USA Inc., Inc. will work in concert with one another to make, use, offer to sell, and/or sell the generic drug products that are the subject of ANDA No. 207939 throughout the United States, and/or import such generic drug products into the United States, including in this judicial district.

126. HEC has committed an act of infringement in this judicial district by filing ANDA No. 207939 with the intent to make, use, offer to sell, and/or sell the generic drug products that are the subject of ANDA No. 207939 in this judicial district, an act of infringement that has led to foreseeable harm and injury to Novartis, a Delaware corporation.

127. HEC has extensive contacts with the State of Delaware, regularly conducts business in the State of Delaware, either directly or through one or more of its wholly owned subsidiaries, agents, and/or alter egos, has purposefully availed itself of the privilege of doing business in the State of Delaware, and intends to sell in the State of Delaware the product described in ANDA No. 207939 upon approval. Furthermore, upon information and belief, HEC has a regular and established place of business in this judicial district.

128. HEC Pharm Group, HEC Pharm Co., Ltd., and HEC Pharm USA Inc. have availed themselves of the legal protections of the State of Delaware by, among other things, admitting jurisdiction and asserting counterclaims in lawsuits filed in the United States District Court for the District of Delaware. *See, e.g., Astrazeneca LP et al. v. HEC Pharm Co., Ltd. et al.*, C.A. No. 15-1041 (D. Del.).

m) Hetero USA Inc.; Hetero Labs Limited Unit-V; Hetero Labs Limited

129. Upon information and belief, Defendant Hetero Labs Limited is a corporation organized and existing under the laws of India, having a principal place of business at 7-2-A2, Hetero Corporate Industrial Estates, Sanath Nagar, Hyderabad 500 018, Andhra Pradesh, India.

130. Upon information and belief, Defendant Hetero Labs Limited Unit-V is a corporation organized and existing under the laws of India, having a principal place of business at Polepally, Jadcherla, Mahabubnagar, 509301, Andhra Pradesh, India.

131. Upon information and belief, Defendant Hetero USA Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 1035 Centennial Avenue, Piscataway, New Jersey 08854.

132. Upon information and belief, Hetero Labs Limited is in the business of, among other things, developing, manufacturing, and selling generic versions of branded pharmaceutical products for the U.S. market. Upon information and belief, Hetero USA Inc. and Hetero Labs Limited Unit-V are wholly-owned subsidiaries of Hetero Labs Limited and are controlled and/or dominated by Hetero Labs Limited. Upon information and belief, Hetero USA Inc. develops, manufactures and/or distributes generic drug products for marketing, sale, and/or

use throughout the United States, including in this judicial district, at the direction, under the control, and for the benefit of Hetero Labs Limited and Hetero Labs Limited Unit-V.

133. Hetero Labs Limited, Hetero Labs Limited Unit-V, and Hetero USA Inc. are collectively referred to hereafter as "Hetero" unless otherwise noted.

134. By a letter dated June 13, 2016, Hetero notified Plaintiff that Hetero had submitted to the FDA ANDA No. 207933 for Fingolimod 0.5 mg capsules, a drug product that is a generic version of GILENYA® ("Hetero's ANDA Product"). The purpose of Hetero's submission of the ANDA was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Hetero's ANDA Product prior to the expiration of the '405 patent.

135. In its Notice Letter, Hetero notified Plaintiff that, as a part of its ANDA, Hetero had filed a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to the '405 patent asserting that the '405 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, and sale of Hetero's ANDA Product.

136. Upon information and belief, and consistent with their past practices, Hetero Labs Limited, Hetero Labs Limited Unit-V, and Hetero USA Inc. acted collaboratively in the preparation and submission of ANDA No. 207933.

137. Upon information and belief, and consistent with their past practices, following any FDA approval of ANDA No. 207933, Hetero Labs Limited, Hetero Labs Limited Unit-V, and Hetero USA Inc., Inc. will work in concert with one another to make, use, offer to sell, and/or sell the generic drug products that are the subject of ANDA No. 207933 throughout

the United States, and/or import such generic drug products into the United States, including in this judicial district.

138. Hetero has committed an act of infringement in this judicial district by filing ANDA No. 207933 with the intent to make, use, offer to sell, and/or sell the generic drug products that are the subject of ANDA No. 207933 in this judicial district, an act of infringement that has led to foreseeable harm and injury to Novartis, a Delaware corporation.

139. Hetero has extensive contacts with the State of Delaware, regularly conducts business in the State of Delaware, either directly or through one or more of its wholly owned subsidiaries, agents, and/or alter egos, has purposefully availed itself of the privilege of doing business in the State of Delaware, and intends to sell in the State of Delaware the product described in ANDA No. 207933 upon approval. Furthermore, upon information and belief, Hetero has a regular and established place of business in this judicial district.

140. Hetero Labs Limited, Hetero Labs Limited Unit-V, and Hetero USA Inc. have availed themselves of the legal protections of the State of Delaware by, among other things, admitting jurisdiction and asserting counterclaims in lawsuits filed in the United States District Court for the District of Delaware. *See, e.g.*, *Biogen International GmbH et al v. Hetero USA Inc. et al.*, 17-00825 (D. Del.), *Bristol-Myers Squibb Company et al v. Hetero USA Inc. et al.*, 17-00376 (D. Del.), *Amgen Inc. v. Hetero USA Inc. et al.*, 16-00928 (D. Del.), *UCB, Inc. et al v. Hetero USA Inc. et al.*, 16-00452 (D. Del.), *Cephalon, Inc. v. Dr. Reddy's Laboratories, Ltd. et al.*, 15-00179 (D. Del.), *AbbVie Inc. et al v. Hetero USA Inc. et al.*, 14-00543 (D. Del.), *Otsuka Pharmaceutical Co. Ltd. v. Hetero USA Inc. et al.*, 14-00421 (D. Del.), and *Teijin Limited et al v. Hetero USA Inc. et al.*, 14-00166 (D. Del.).

n) Mylan Pharmaceuticals, Inc.

141. Upon information and belief, Defendant Mylan Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of West Virginia, having a principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505.

142. Upon information and belief, Mylan Pharmaceuticals, Inc. is in the business of, among other things, developing, manufacturing, and selling generic versions of branded pharmaceutical products for the U.S. market, including in this district.

143. Mylan Pharmaceuticals, Inc. is referred to hereafter as "Mylan" unless otherwise noted.

144. By a letter dated April 6, 2016, Mylan notified Plaintiff that Mylan had submitted to the FDA ANDA No. 208005 for Fingolimod 0.5 mg capsules, a drug product that is a generic version of GILENYA® ("Mylan's ANDA Product"). The purpose of Mylan's submission of the ANDA was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Mylan's ANDA Product prior to the expiration of the '405 patent.

145. In its Notice Letter, Mylan notified Plaintiff that, as a part of its ANDA, Mylan had filed a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to the '405 patent asserting that the '405 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, and sale of Mylan's ANDA Product.

146. Upon information and belief, and consistent with its past practices, following any FDA approval of ANDA No. 208005, Mylan will make, use, offer to sell, and/or sell the generic drug products that are the subject of ANDA No. 208005 throughout the United

States, and/or import such generic drug products into the United States, including in this judicial district.

147. Mylan has committed an act of infringement in this judicial district by filing ANDA No. 208005 with the intent to make, use, offer to sell, and/or sell the generic drug products that are the subject of ANDA No. 208005 in this judicial district, an act of infringement that has led to foreseeable harm and injury to Novartis, a Delaware corporation.

148. Mylan has extensive contacts with the State of Delaware, regularly conducts business in the State of Delaware, either directly or through one or more of its wholly owned subsidiaries, agents, and/or alter egos, has purposefully availed itself of the privilege of doing business in the State of Delaware, and intends to sell in the State of Delaware the product described in ANDA No. 208005 upon approval. Furthermore, upon information and belief, Mylan has a regular and established place of business in this judicial district.

149. Mylan has availed itself of the legal protections of the State of Delaware by, among other things, admitting jurisdiction and asserting counterclaims in lawsuits filed in the United States District Court for the District of Delaware. As this Court has noted, Mylan Pharmaceuticals, Inc. "appears in front of this Court with regularity for the purpose of getting its generic drugs on the market, and when that litigation concludes in a way that is favorable for MPI, those generic drugs are distributed to and used by Delaware residents through a distribution network that has been established for that purpose." *See Bristol-Myers Squibb Co. v. Mylan Pharm. Inc.*, D.I. 36 at 38, C.A. No. 17-379-LPS (D. Del. 2017). Furthermore, "[f]or at least the past ten years, there has been at least one Mylan action pending in this District at any given time," (*see id.* at 36), several of which include a Mylan entity as the plaintiff or counter claimant. *See, also e.g., Javelin Pharm., Inc. et al v. Mylan Labs. Ltd.*, C.A. No. 16-00554 (D. Del.);

Mylan Pharm., Inc. v. Galderma Labs. Inc., C.A. No. 10-00892 (D. Del.); *Mylan Pharm., Inc. v. Ethypharm SA*, C.A. No. 10-1064 (D. Del.); *Mylan Pharm., Inc. et al v. Eurand Inc.*, C.A. No. 10-306 (D. Del.); *Mylan, Inc. et al v. Boehringer Ingelheim Intern'l GMBH*, C.A. No. 10-244 (D. Del.).

o) Nostrum Laboratories Inc., USA; Nostrum Pharmaceuticals, LLC; MSN Laboratories Private Limited; MSN Pharmaceuticals Inc.

150. Upon information and belief, Defendant Nostrum Pharmaceuticals, LLC is a limited liability company organized and existing under the laws of the State of Delaware, having a principal place of business at 11D Jules Lane, New Brunswick, NJ 08901.

151. Upon information and belief, Defendant Nostrum Laboratories Inc., USA is a corporation organized and existing under the laws of the State of New Jersey, having a principal place of business at 1800 N Topping Ave., Kansas City, MO 64120.

152. Upon information and belief, MSN Laboratories Private Limited is a corporation organized and existing under the laws of India, having a principal place of business at MSN House Plot No. C-24, Industrial Estate, Sanath Nagar, Hyderabad 500018, India.

153. Upon information and belief, Defendant MSN Pharmaceuticals Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 343 Thornall Street, Suite 678, Edison, New Jersey 08837.

154. Upon information and belief, Nostrum Pharmaceuticals, LLC is in the business of, among other things, developing, manufacturing, and selling generic versions of branded pharmaceutical products for the U.S. market. Upon information and belief, Nostrum Laboratories Inc., USA is a wholly-owned subsidiary of Nostrum Pharmaceuticals, LLC and is controlled and/or dominated by Nostrum Pharmaceuticals, LLC. Upon information and belief,

Nostrum Laboratories Inc., USA develops, manufactures and/or distributes generic drug products for marketing, sale, and/or use throughout the United States, including in this judicial district, at the direction, under the control, and for the benefit of Nostrum Pharmaceuticals, LLC.

155. Nostrum Pharmaceuticals, LLC and Nostrum Laboratories Inc., USA are collectively referred to hereafter as "Nostrum" unless otherwise noted.

156. Upon information and belief, MSN Laboratories Private Limited is in the business of, among other things, developing, manufacturing, and selling generic versions of branded pharmaceutical products for the U.S. market. Upon information and belief, MSN Pharmaceuticals Inc. is a wholly-owned subsidiary of MSN Laboratories Private Limited and is controlled and/or dominated by MSN Laboratories Private Limited. Upon information and belief, MSN Pharmaceuticals Inc. develops, manufactures and/or distributes generic drug products for marketing, sale, and/or use throughout the United States, including in this judicial district, at the direction, under the control, and for the benefit of MSN Laboratories Private Limited.

157. MSN Laboratories Private Limited and MSN Pharmaceuticals Inc. are collectively referred to hereafter as "MSN" unless otherwise noted.

158. By a letter dated April 7, 2016, Nostrum and MSN notified Plaintiff that Nostrum and MSN had submitted to the FDA ANDA No. 208559 for Fingolimod 0.5 mg capsules, a drug product that is a generic version of GILENYA® ("Nostrum and MSN's ANDA Product"). The purpose of Nostrum and MSN's submission of the ANDA was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Nostrum and MSN's ANDA Product prior to the expiration of the '405 patent.

159. In their Notice Letter, Nostrum and MSN notified Plaintiff that, as a part of their ANDA, Nostrum and MSN had filed a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to the '405 patent asserting that the '405 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, and sale of Nostrum and MSN's ANDA Product.

160. Upon information and belief, and consistent with their past practices, Nostrum Pharmaceuticals, LLC, Nostrum Laboratories Inc., USA, MSN Laboratories Private Limited, and MSN Pharmaceuticals Inc. acted collaboratively in the preparation and submission of ANDA No. 208559.

161. Upon information and belief, and consistent with their past practices, following any FDA approval of ANDA No. 208559, Nostrum Pharmaceuticals, LLC, Nostrum Laboratories Inc., USA, MSN Laboratories Private Limited, and MSN Pharmaceuticals Inc. will work in concert with one another to make, use, offer to sell, and/or sell the generic drug products that are the subject of ANDA No. 208559 throughout the United States, and/or import such generic drug products into the United States, including in this judicial district.

162. Nostrum and MSN have committed an act of infringement in this judicial district by filing ANDA No. 208559 with the intent to make, use, offer to sell, and/or sell the generic drug products that are the subject of ANDA No. 208559 in this judicial district, an act of infringement that has led to foreseeable harm and injury to Novartis, a Delaware corporation.

163. Nostrum and MSN have extensive contacts with the State of Delaware, regularly conduct business in the State of Delaware, either directly or through one or more of their wholly owned subsidiaries, agents, and/or alter egos, have purposefully availed themselves of the privilege of doing business in the State of Delaware, and intend to sell in the State of

Delaware the product described in ANDA No. 208559 upon approval. Furthermore, upon information and belief, Nostrum and MSN have a regular and established place of business in this judicial district.

164. MSN Laboratories Private Limited, and MSN Pharmaceuticals Inc. have availed themselves of the legal protections of the State of Delaware by, among other things, admitting jurisdiction and asserting counterclaims in lawsuits filed in the United States District Court for the District of Delaware. *See, e.g., Biogen International GmbH v. MSN Laboratories Private Ltd., et al.*, 18-0337 (D. Del.); *H. Lundbeck A/S, et al. v. MSN Laboratories Private Limited, et al.*, 18-0114 (D. Del.); *Adverio Pharma GmbH, et al. v. MSN Laboratories Private Limited, et al.*, 18-0111 (D. Del.); *Onyx Therapeutics, Inc. v. MSN Pharmaceuticals, Inc., et al.*, 17-1833 (D. Del.); *Wyeth LLC, et al. v. MSN Laboratories Private Limited, et al.*, 17-0233 (D. Del.).

p) Par Pharmaceutical Inc.

165. Upon information and belief, Defendant Par Pharmaceutical Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at One Ram Ridge Road, Spring Valley, New York 10977.

166. Upon information and belief, Par Pharmaceutical Inc. is in the business of, among other things, developing, manufacturing, and selling generic versions of branded pharmaceutical products for the U.S. market, including in this district.

167. Par Pharmaceutical Inc. is referred to hereafter as "Par" unless otherwise noted.

168. By a letter dated October 17, 2016, Par notified Plaintiff that Par had submitted to the FDA ANDA No. 207965 for Fingolimod 0.5 mg capsules, a drug product that is

a generic version of GILENYA® ("Par's ANDA Product"). The purpose of Par's submission of the ANDA was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Par's ANDA Product prior to the expiration of the '405 patent.

169. In its Notice Letter, Par notified Plaintiff that, as a part of its ANDA, Par had filed a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to the '405 patent asserting that the '405 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, and sale of Par's ANDA Product.

170. Upon information and belief, and consistent with its past practices, following any FDA approval of ANDA No. 207965, Par will make, use, offer to sell, and/or sell the generic drug products that are the subject of ANDA No. 207965 throughout the United States, and/or import such generic drug products into the United States, including in this judicial district.

171. Par has committed an act of infringement in this judicial district by filing ANDA No. 207965 with the intent to make, use, offer to sell, and/or sell the generic drug products that are the subject of ANDA No. 207965 in this judicial district, an act of infringement that has led to foreseeable harm and injury to Novartis, a Delaware corporation.

172. Par has extensive contacts with the State of Delaware, regularly conducts business in the State of Delaware, either directly or through one or more of its wholly owned subsidiaries, agents, and/or alter egos, has purposefully availed itself of the privilege of doing business in the State of Delaware, and intends to sell in the State of Delaware the product described in ANDA No. 207965 upon approval. Furthermore, upon information and belief, Par has a regular and established place of business in this judicial district.

173. Par has availed itself of the legal protections of the State of Delaware by, among other things, admitting jurisdiction and asserting counterclaims in lawsuits filed in the United States District Court for the District of Delaware. *See, e.g.*, *Par Pharmaceutical, Inc. et al. v. Hospira, Inc.*, C.A. No. 17-944 (D. Del.); *Reckitt Benckiser et al. v. Par Pharmaceutical, Inc. et al.*, C.A. No. 13-1674 (D. Del.); *Novartis Pharmaceuticals Corp. v. Par Pharmaceutical, Inc.*, C.A. No. 15-1050 (D. Del.).

q) Prinston Pharmaceutical Inc.

174. Upon information and belief, Defendant Prinston Pharmaceutical Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 2002 Eastpark Blvd., Cranbury, NJ 08512.

175. Upon information and belief, Prinston Pharmaceutical Inc. is in the business of, among other things, developing, manufacturing, and selling generic versions of branded pharmaceutical products for the U.S. market, including in this district.

176. Prinston Pharmaceutical Inc. is referred to hereafter as "Prinston" unless otherwise noted.

177. By a letter dated April 28, 2017, Prinston notified Plaintiff that Prinston had submitted to the FDA ANDA No. 208003 for Fingolimod 0.5 mg capsules, a drug product that is a generic version of GILENYA® ("Prinston's ANDA Product"). The purpose of Prinston's submission of the ANDA was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Prinston's ANDA Product prior to the expiration of the '405 patent.

178. In its Notice Letter, Prinston notified Plaintiff that, as a part of its ANDA, Prinston had filed a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the

FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to the '405 patent asserting that the '405 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, and sale of Prinston's ANDA Product.

179. Upon information and belief, and consistent with its past practices, following any FDA approval of ANDA No. 208003, Prinston will make, use, offer to sell, and/or sell the generic drug products that are the subject of ANDA No. 208003 throughout the United States, and/or import such generic drug products into the United States, including in this judicial district.

180. Prinston has committed an act of infringement in this judicial district by filing ANDA No. 208003 with the intent to make, use, offer to sell, and/or sell the generic drug products that are the subject of ANDA No. 208003 in this judicial district, an act of infringement that has led to foreseeable harm and injury to Novartis, a Delaware corporation.

181. Prinston has extensive contacts with the State of Delaware, regularly conducts business in the State of Delaware, either directly or through one or more of its wholly owned subsidiaries, agents, and/or alter egos, has purposefully availed itself of the privilege of doing business in the State of Delaware, and intends to sell in the State of Delaware the product described in ANDA No. 208003 upon approval. Furthermore, upon information and belief, Prinston has a regular and established place of business in this judicial district.

182. Prinston has availed itself of the legal protections of the State of Delaware by, among other things, admitting jurisdiction and asserting counterclaims in lawsuits filed in the United States District Court for the District of Delaware. *See, e.g.*, *Astellas Pharma Inc. et al. v. Prinston Pharm. Inc.*, No. 1:16-00943 (D. Del.); *AstraZeneca LP et al. v. Prinston Pharm. Inc.*,

No. 15-01057(D. Del.); *Bayer Intell. Prop. GMBH et al. v. Aurobindo Pharma Ltd. et al.*, No. 15-00902- (D. Del.); *Teijin Ltd. et al. v. Prinston Pharm. Inc.*, No. 14-00854 (D. Del.).

r) Strides Global Pharma Private Limited; Strides Pharma, Inc.

183. Upon information and belief, Defendant Strides Global Pharma Private Limited is a corporation organized and existing under the laws of Singapore, having a principal place of business at No. 8 Eu Tong Sen Street, #15-93, The Central, Singapore—059818.

184. Upon information and belief, Defendant Strides Pharma, Inc. is a corporation organized and existing under the laws of the State of New Jersey, having a principal place of business at 2 Tower Center Blvd., Suite 1102, East Brunswick, NJ 08816.

185. Upon information and belief, Strides Global Pharma Private Limited is in the business of, among other things, developing, manufacturing, and selling generic versions of branded pharmaceutical products for the U.S. market. Upon information and belief, Strides Pharma, Inc. is a wholly-owned subsidiary of Strides Global Pharma Private Limited and is controlled and/or dominated by Strides Global Pharma Private Limited. Upon information and belief, Strides Pharma, Inc. develops, manufactures and/or distributes generic drug products for marketing, sale, and/or use throughout the United States, including in this judicial district, at the direction, under the control, and for the benefit of Strides Global Pharma Private Limited.

186. Strides Global Pharma Private Limited and Strides Pharma, Inc. are collectively referred to hereafter as "Strides" unless otherwise noted.

187. By a letter dated January 22, 2016, Strides notified Plaintiff that Strides had submitted to the FDA ANDA No. 207971 for Fingolimod 0.5 mg capsules, a drug product that is a generic version of GILENYA® ("Strides's ANDA Product"). The purpose of Strides's submission of the ANDA was to obtain approval under the FDCA to engage in the commercial

manufacture, use, offer for sale, and/or sale of Strides's ANDA Product prior to the expiration of the '405 patent.

188. In its Notice Letter, Strides notified Plaintiff that, as a part of its ANDA, Strides had filed a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to the '405 patent asserting that the '405 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, and sale of Strides's ANDA Product.

189. Upon information and belief, and consistent with their past practices, Strides Global Pharma Private Limited and Strides Pharma, Inc. acted collaboratively in the preparation and submission of ANDA No. 207971.

190. Upon information and belief, and consistent with their past practices, following any FDA approval of ANDA No. 207971, Strides Global Pharma Private Limited and Strides Pharma, Inc. will work in concert with one another to make, use, offer to sell, and/or sell the generic drug products that are the subject of ANDA No. 207971 throughout the United States, and/or import such generic drug products into the United States, including in this judicial district.

191. Strides has committed an act of infringement in this judicial district by filing ANDA No. 207971 with the intent to make, use, offer to sell, and/or sell the generic drug products that are the subject of ANDA No. 207971 in this judicial district, an act of infringement that has led to foreseeable harm and injury to Novartis, a Delaware corporation.

192. Strides has extensive contacts with the State of Delaware, regularly conducts business in the State of Delaware, either directly or through one or more of its wholly owned subsidiaries, agents, and/or alter egos, has purposefully availed itself of the privilege of

doing business in the State of Delaware, and intends to sell in the State of Delaware the product described in ANDA No. 207971 upon approval. Furthermore, upon information and belief, Strides has a regular and established place of business in this judicial district.

193. Strides Global Pharma Private Limited and Strides Pharma, Inc. have availed themselves of the legal protections of the State of Delaware by, among other things, admitting jurisdiction and asserting counterclaims in lawsuits filed in the United States District Court for the District of Delaware. *See, e.g.*, *Forest Laboratories Holdings, Ltd. et al. v. Strides Pharma Global PTE Limited et al.*, C.A. No. 17-01394 (D. Del.); *Amgen Inc., v. Strides Pharma Global PTE Limited et al.*, C.A. No. 16-00881 (D. Del.); *Takeda Pharmaceuticals U.S.A., Inc. v. Strides Pharma Global PTE Limited et al.*, C.A. No. 17-01690 (D. Del.).

s) Torrent Pharma Inc.; Torrent Pharmaceuticals Ltd.

194. Upon information and belief, Defendant Torrent Pharmaceuticals Ltd. is a corporation organized and existing under the laws of India, having a principal place of business at Off. Ashram Road, Ahmedabad – 380 009, Gujarat, India.

195. Upon information and belief, Defendant Torrent Pharma Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 150 Allen Road, Suite 102, Basking Ridge, New Jersey 07920.

196. Upon information and belief, Torrent Pharmaceuticals Ltd. is in the business of, among other things, developing, manufacturing, and selling generic versions of branded pharmaceutical products for the U.S. market. Upon information and belief, Torrent Pharma Inc. is a wholly-owned subsidiary of Torrent Pharmaceuticals Ltd. and is controlled and/or dominated by Torrent Pharmaceuticals Ltd.. Upon information and belief, Torrent Pharma Inc. develops, manufactures and/or distributes generic drug products for marketing, sale,

and/or use throughout the United States, including in this judicial district, at the direction, under the control, and for the benefit of Torrent Pharmaceuticals Ltd.

197. Torrent Pharmaceuticals Ltd. and Torrent Pharma Inc. are collectively referred to hereafter as "Torrent" unless otherwise noted.

198. By a letter dated May 1, 2017, Torrent notified Plaintiff that Torrent had submitted to the FDA ANDA No. 208001 for Fingolimod 0.5 mg capsules, a drug product that is a generic version of GILENYA® ("Torrent's ANDA Product"). The purpose of Torrent's submission of the ANDA was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Torrent's ANDA Product prior to the expiration of the '405 patent.

199. In its Notice Letter, Torrent notified Plaintiff that, as a part of its ANDA, Torrent had filed a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to the '405 patent asserting that the '405 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, and sale of Torrent's ANDA Product.

200. Upon information and belief, and consistent with their past practices, Torrent Pharmaceuticals Ltd. and Torrent Pharma Inc. acted collaboratively in the preparation and submission of ANDA No. 208001.

201. Upon information and belief, and consistent with their past practices, following any FDA approval of ANDA No. 208001, Torrent Pharmaceuticals Ltd. and Torrent Pharma Inc., Inc. will work in concert with one another to make, use, offer to sell, and/or sell the generic drug products that are the subject of ANDA No. 208001 throughout the United States, and/or import such generic drug products into the United States, including in this judicial district.

202. Torrent has committed an act of infringement in this judicial district by filing ANDA No. 208001 with the intent to make, use, offer to sell, and/or sell the generic drug products that are the subject of ANDA No. 208001 in this judicial district, an act of infringement that has led to foreseeable harm and injury to Novartis, a Delaware corporation.

203. Torrent has extensive contacts with the State of Delaware, regularly conducts business in the State of Delaware, either directly or through one or more of its wholly owned subsidiaries, agents, and/or alter egos, has purposefully availed itself of the privilege of doing business in the State of Delaware, and intends to sell in the State of Delaware the product described in ANDA No. 208001 upon approval. Furthermore, upon information and belief, Torrent has a regular and established place of business in this judicial district.

204. Torrent Pharmaceuticals Ltd. and Torrent Pharma Inc. have availed themselves of the legal protections of the State of Delaware by, among other things, admitting jurisdiction and asserting counterclaims in lawsuits filed in the United States District Court for the District of Delaware. *See, e.g., H. Lundbeck A/S, et al. v. Torrent Pharmaceuticals Limited, et al.*, 18-0672 (D. Del.); *Bial - Portela & Ca., et al. v. Torrent Pharmaceuticals Ltd., et al.*, 18-0279 (D. Del.); *H. Lundbeck A/S, et al. v. Torrent Pharmaceuticals Limited, et al.*, 18-0149 (D. Del.); *Bayer Intellectual Property GmbH, et al. v. Torrent Pharmaceuticals, Limited, et al.*, 17-1163 (D. Del.); *Bristol-Myers Squibb Company, et al. v. Torrent Pharmaceuticals Ltd.*, 17-0381 (D. Del.).

t) Zydus Pharmaceuticals (USA) Inc.; Cadila Healthcare Limited

205. Upon information and belief, Defendant Cadila Healthcare Limited is a corporation organized and existing under the laws of India, having a principal place of business at Zydus Tower, Satellite Cross Roads, Ahmedabad-380015, Gujarat, India.

206. Upon information and belief, Defendant Zydus Pharmaceuticals (USA) Inc. is a corporation organized and existing under the laws of the State of New Jersey, having a principal place of business at 73 Route 31 North, Pennington, NJ 08534.

207. Upon information and belief, Cadila Healthcare Limited is in the business of, among other things, developing, manufacturing, and selling generic versions of branded pharmaceutical products for the U.S. market. Upon information and belief, Zydus Pharmaceuticals (USA) Inc. is a wholly-owned subsidiary of Cadila Healthcare Limited and is controlled and/or dominated by Cadila Healthcare Limited. Upon information and belief, Zydus Pharmaceuticals (USA) Inc. develops, manufactures and/or distributes generic drug products for marketing, sale, and/or use throughout the United States, including in this judicial district, at the direction, under the control, and for the benefit of Cadila Healthcare Limited.

208. Cadila Healthcare Limited and Zydus Pharmaceuticals (USA) Inc. are collectively referred to hereafter as "Zydus" unless otherwise noted.

209. By a letter dated August 19, 2016, Zydus notified Plaintiff that Zydus had submitted to the FDA ANDA No. 207994 for Fingolimod 0.5 mg capsules, a drug product that is a generic version of GILENYA® ("Zydus's ANDA Product"). The purpose of Zydus's submission of the ANDA was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Zydus's ANDA Product prior to the expiration of the '405 patent.

210. In its Notice Letter, Zydus notified Plaintiff that, as a part of its ANDA, Zydus had filed a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to the '405 patent asserting that the '405

patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, and sale of Zydus's ANDA Product.

211. Upon information and belief, and consistent with their past practices, Cadila Healthcare Limited and Zydus Pharmaceuticals (USA) Inc. acted collaboratively in the preparation and submission of ANDA No. 207994.

212. Upon information and belief, and consistent with their past practices, following any FDA approval of ANDA No. 207994, Cadila Healthcare Limited and Zydus Pharmaceuticals (USA) Inc. will work in concert with one another to make, use, offer to sell, and/or sell the generic drug products that are the subject of ANDA No. 207994 throughout the United States, and/or import such generic drug products into the United States, including in this judicial district.

213. Zydus has committed an act of infringement in this judicial district by filing ANDA No. 207994 with the intent to make, use, offer to sell, and/or sell the generic drug products that are the subject of ANDA No. 207994 in this judicial district, an act of infringement that has led to foreseeable harm and injury to Novartis, a Delaware corporation.

214. Zydus has extensive contacts with the State of Delaware, regularly conducts business in the State of Delaware, either directly or through one or more of its wholly owned subsidiaries, agents, and/or alter egos, has purposefully availed itself of the privilege of doing business in the State of Delaware, and intends to sell in the State of Delaware the product described in ANDA No. 207994 upon approval. Furthermore, upon information and belief, Zydus has a regular and established place of business in this judicial district.

215. Cadila Healthcare Limited and Zydus Pharmaceuticals (USA) Inc. have availed themselves of the legal protections of the State of Delaware by, among other things,

admitting jurisdiction and asserting counterclaims in lawsuits filed in the United States District Court for the District of Delaware. *See, e.g.*, *Millennium Pharm., Inc. v. Zydus Pharm. (USA) Inc. et al.*, C.A. No. 17-00423 (D. Del.); *Sanofi-Aventis U.S. LLC et al. v. Zydus Pharm. (USA) Inc. et al.*, C.A. No. 17-00034 (D. Del.); *Astellas Pharma, Inc. et al. v. Zydus Pharm. (USA) Inc. et al.*, C.A. No. 16-01167 (D. Del.); *Amgen Inc. v. Zydus Pharm. (USA) Inc. et al.*, C.A. No. 16-00853 (D. Del.); *Genzyme Corp. et al. v. Zydus Pharm. (USA) Inc.*, C.A. No. 16- 00540 (D. Del.); *Upsher-Smith Labs, Inc. v. Zydus Pharm. (USA) Inc. et al.*, C.A. No. 16-00248 (D. Del.).

JURISDICTION AND VENUE

216. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100, *et seq.*, and this Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a). Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b).

217. This Court has personal jurisdiction over each Defendant because, among other things, each has committed, or aided, abetted, contributed to, or participated in the commission of, tortious acts of patent infringement in filing each ANDA that has led to foreseeable harm and injury to Novartis, a Delaware corporation.

218. This Court also has personal jurisdiction over each Defendant because each of its affiliations with the State of Delaware, including in many instances by virtue of its incorporation in Delaware or the incorporation in Delaware of subsidiaries, are so continuous and systematic as to render each Defendant essentially at home in this forum.

219. This Court also has personal jurisdiction over each Defendant because each has frequently availed itself of the legal protections of the State of Delaware by, among other things, selecting the State of Delaware as the place of incorporation for itself and their

subsidiaries and admitting jurisdiction and asserting counterclaims in lawsuits filed in the United States District Court for the District of Delaware.

220. For these reasons, and for other reasons that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiction over each Defendant.

221. Venue is proper in this Court because, among other things, each Defendant is *inter alia* incorporated in the State of Delaware and therefore "resides" in this judicial district and/or has committed acts of infringement in this district and has a regular and established place of business in this district. 28 U.S.C. § 1400(b). Those defendants that are foreign corporations not residing in any United States judicial district may be sued in any judicial district. 28 U.S.C. § 1391(c)(3). Moreover, the Defendants have litigated previous Hatch-Waxman patent infringement disputes in the District of Delaware.

THE PATENT-IN-SUIT AND GILENYA®

222. On November 17, 2015, the U.S. Patent and Trademark Office duly and legally issued the '405 patent, entitled "S1P Receptor Modulators for Treating Relasping[*sic*]-Remitting Multiple Sclerosis." A true and correct copy of the '405 patent is attached hereto as **Exhibit A**.

223. The claims of the '405 patent are valid and enforceable, as recently held by the United States Patent and Trademark Office in its Final Written Decision following *inter partes* review. *See* **Exhibit B** (IPR2018-00854, Paper 109). The '405 patent is wholly owned by Novartis, who therefore has the right to sue for and obtain equitable relief and damages for infringement of the '405 patent.

224. Novartis is the holder of New Drug Application ("NDA") No. 022527 by which the FDA granted approval for the commercial manufacturing, marketing, sale, and use of

GILENYA® (fingolimod) Capsules, 0.5 mg. GILENYA® is the first in a new class of compounds known as sphingosine 1-phosphate receptor (S1PR) modulators. GILENYA® is indicated for the treatment of relapsing forms of multiple sclerosis (MS) in patients 10 years of age and older. GILENYA® is the first oral drug that has been approved by the FDA for such an indication.

225. GILENYA® and the use of GILENYA® is covered by one or more claims of the '405 patent.

226. The FDA's official publication of approved drugs (the "Orange Book") lists the '405 patent in connection with GILENYA®.

INFRINGEMENT BY EACH DEFENDANT OF THE PATENT-IN-SUIT

227. Plaintiff incorporates each of the proceeding paragraphs 1 – 226 as if fully set forth herein.

228. Each Defendant, or group of Defendants, by filing its ANDA, has necessarily represented to the FDA that, upon approval, its ANDA Product will have the same active ingredient, method of administration, dosage form, and dosage amount as GILENYA®, and will be bioequivalent to GILENYA®.

229. Each Defendant's or group of Defendants ANDA submission seeking approval to engage in the commercial manufacture, use, offer to sell, or sale of its ANDA Product, prior to the expiration of the '405 patent constitutes infringement of one or more of the claims of the '405 patent under 35 U.S.C. § 271(e)(2)(A).

230. Upon information and belief, each Defendant or group of Defendants intends to engage in the commercial manufacture, use, offer for sale, sale, marketing,

distributing, and/or importation of its ANDA Product with the respective proposed labeling immediately and imminently upon approval of its ANDA.

231. Upon information and belief, each ANDA Product's proposed labeling will be substantially identical to the GILENYA® label, and the GILENYA® label discloses all elements of at least claim 1 of the '405 patent. Thus, upon information and belief, each ANDA Product labeling will disclose all elements of at least claim 1 of the '405 patent, therefore showing that use by, for example patients and/or healthcare providers of each ANDA Product in accordance with its proposed labeling will infringe at least claim 1 of the '405 patent.

232. The commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of each ANDA Product would infringe one or more claims of the '405 patent.

233. Upon information and belief, use of each ANDA Product in accordance with and as directed by the respective proposed labeling for each ANDA Product would infringe one or more claims of the '405 patent.

234. Upon information and belief, each Defendant or group of Defendants has actual knowledge of the '405 patent and plans and intends to, and will, actively induce infringement of the '405 patent when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

235. Upon information and belief, each Defendant or group of Defendants knows that its ANDA Product is especially made or adapted for use in infringing the '405 patent, and that each Defendant's ANDA Product is not suitable for any substantial non-infringing use. Upon information and belief, each Defendant or group of Defendants plans and intends to, and

will, contribute to the infringement of the ’405 patent immediately and imminently upon approval of its respective ANDA.

236. The foregoing acts by each Defendant or group of Defendants constitutes and/or will constitute infringement of the ’405 patent, active inducement of infringement of the ’405 patent, and/or contribution to the infringement by others of the ’405 patent under 35 U.S.C. §§ 271(a)–(c).

237. Upon information and belief, each Defendant or group of Defendants acted without a reasonable basis for believing that it would not be liable for infringing the ’405 patent, active inducement of infringement of the ’405 patent, and/or contribution to the infringement by others of the ’405 patent.

238. If each Defendant’s infringement of the ’405 patent is not enjoined, Plaintiff will suffer substantial and irreparable harm for which there is no remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Novartis prays that this Court grant the following relief:

1. A judgment that one or more claims of the ’405 patent is not invalid, is enforceable, and is infringed by each Defendant’s ANDA submission, and that each Defendant’s making, using, offering to sell, or selling in the United States, or importing into the United States of its respective ANDA Product will infringe the ’405 patent.

2. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of each Defendant’s ANDA shall be a date not earlier than the expiration date of the ’405 patent, including any extensions and/or additional periods of exclusivity to which Novartis is or becomes entitled.

3. An order enjoining each Defendant, its affiliates, subsidiaries, and each of their officers, agents, servants and employees and those acting in privity or in concert with each Defendant, from making, using, offering to sell, or selling in the United States, or importing into the United States its respective ANDA Product, until after the expiration date of the '405 patent, including any extensions and/or additional periods of exclusivity to which Novartis is or becomes entitled.

4. Damages, including monetary and other relief, to Novartis if any Defendant engages in commercial manufacture, use, offers to sell, sale, or importation in or into the United States of its ANDA Product, prior to the expiration date of the '405 patent, including any extensions and/or additional periods of exclusivity to which Novartis is or becomes entitled.

5. Such further and other relief as this Court deems proper and just, including any appropriate relief under 35 U.S.C. § 285.

Dated: July 16, 2018

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